

REMARKS

This is a full and timely response to the outstanding non-final Office action of April 18, 2008. The Examiner has required the applicant to elect to prosecute one of two (2) groups of claims identified in the Office Action. In response to the restriction requirement, applicant respectfully elects to prosecute the claims of Group I, corresponding to claims 17-26, with traverse, as set out hereafter.

First, in the interests of equity and fairness, applicant should be entitled to pursue different types of claims in the present application, particularly, apparatus claims and method claims, for the invention to fully protect the invention, because there is a different body of law pertaining to each of these different types of claims. The restriction requirement is therefore unfair to the applicant, because it will require the applicant to file and bear the additional cost and time delay associated with filing one or more divisional or continuing applications in order to cover each type of claim set.

Second, as provided in 35 U.S.C. § 121, restriction to one of two or more claimed inventions is proper only if the inventions are "independent and distinct." In its discussion of the propriety of restrictions, MPEP § 803 further provides that if search and examination of two or more inventions can be made without "serious burden," the Examiner must examine them on the merits even if the claims are directed to distinct or independent inventions.

The present disclosure relates to a very specific implant. As explained in the description, because of its important size (which is correlated to its therapeutic function: to fill the stomach of an obese patient), it must be tightly folded for implantation via the mouth and esophagus; once positioned in the stomach, it should be able to expand easily and properly when filled with fluid.

Then, it must keep its volume constant over a long period of time, *i.e.* at least six (6) months, which means that no fluid leakage (*i.e.* no porosity) can be tolerated.

The Office takes the position that the inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is a flexible bag or balloon coated with parylene inserted into the stomach to treat obesity. This element cannot be a special technical feature under PCT Rule 13.2 because the special technical feature lacks novelty and an inventive step because it is disclosed by the combination of U.S. Patent No. 4,694,827 and U.S. Patent No. 5,976,178. U. S. Patent No. 4,694,827 teaches the use of a flexible balloon used for treating obesity as referred to in claims 17 and 27. U.S. Patent No. 5,976,178 teaches a graft structure having a coating of parylene on both inside and outside of the tube, as discussed in claims 17 and 27, to enhance bio-compatibility and a high degree of smoothness.

In the present case, Groups I and II, although not necessarily obvious in view of each other, are very similar in subject matter. More specifically, each pertains to solving the problem of providing an intra-gastric balloon which can be easily implanted and deployed in the stomach, and which is able to maintain its volume constant over a long period of time. The reasoning employed by the Office for requiring restriction is faulty. Ostensibly, the “special technical feature lacks novelty and an inventive step”. The below discussion refutes this assertion and will demonstrate that there is no “serious burden” on the Office. The claims in Groups I and II (as defined by the Office), are not “independent and distinct” when applying 35 U.S.C. § 121. Restriction itself in the instant case is not proper but improper.

Hence, the question to be answered for assessing inventive step is whether there is any teaching in U.S. Patent No. 5,976,178 (“the ‘178 patent”) that would have prompted the skilled person, faced with the above-mentioned technical problem, to modify or adapt the intra-gastric balloon of U.S. Patent No. 4,694,827 (“the ‘827 patent”) while taking account of that teaching, thereby arriving at a balloon falling within the terms of the claims, and thus achieving what the invention achieves.

In other words, the point is not whether the skilled person could have arrived at the invention by adapting or modifying the intra-gastric balloon of the ‘827 patent, but whether he would have done so because the teaching of the ‘178 patent incited him to do so in hopes of solving the objective technical problem.

If the above objective approach for assessing inventive step is applied, one can only arrive at the following conclusions. The skilled person would not have identified the ‘178 patent. Indeed, the ‘178 patent relates to an implant (graft) that has nothing in common with an intra-gastric balloon. Actually, a graft is of very small size (while an intra-gastric balloon is bulky), and is preferably made porous (see col. 3, lines 13-21) while most of all an intra-gastric balloon should not be porous to avoid any fluid leakage. A graft is a surgical implant while an intra-gastric balloon is a medical implant that is intended to be implanted via natural passageways (mouth and esophagus).

Furthermore, there is nothing in the ‘178 patent that allows the skilled person to establish a link between the goals to be reached (decreasing porosity and facilitating folding and deployment) and the parylene.

Actually, the word “parylene” is mentioned only at col. 19, line 47 of the ‘178 patent, among a long list of other possible coatings, and no specific information is given about its

properties, except that it is commonly used to coat pacemakers, which is irrelevant for the skilled person wanting to improve an intra-gastric balloon. One cannot even be sure, reading the '178 patent, that "the very high degree of bio-compatibility and smoothness" are associated with parylene, being understood that these properties are nevertheless irrelevant for the person skilled in the art wanting to solve the above-mentioned technical problem. Thus, the skilled person is absolutely not encouraged to follow the vague teaching of this patent. In other words, the '178 patent gives no hint as to why to specifically choose parylene.

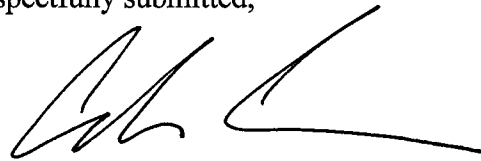
The Office has identified the '178 patent because it was searching for implants coated with parylene, thereby using foreknowledge of the invention. There is no reason for one skilled in the art, unless using foreknowledge of the invention, to search for implants coated with parylene in the prior art, being furthermore noted that there are plenty of different coatings available, the parylene being one coating amongst thousands of other coatings (see e.g., col. 19, lines 41-54).

Furthermore, the skilled person would have been deterred from following the teachings of the '178 patent, since this patent is directed to an implant that is made porous for improving its bio-utility (see col. 3, lines 31-21). In contrast, Applicant's balloon must not be porous for the reasons mentioned above.

For these reasons, the Applicant respectfully submits that the inventions described in these claims are not "independent" as defined in MPEP § 803 and that the restriction requirement therefore is improper as between Groups I and II. Indeed, it appears that a search for apparatus and method would be conducted within the *same class*. In such a situation, it clearly would not be overly burdensome on the Office to check for both of these "separate" inventions at the same time.

For at least the foregoing reasons, Applicant respectfully traverses the restriction requirement and respectfully requests the Examiner to examine the claims of Groups I and II together. Applicant expressly reserves the right to present the non-elected claims, or variants thereof, in continuing applications to be filed subsequent to the present application. Should the Examiner have any questions regarding this response, the Examiner is invited to telephone the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Crain', written over a horizontal line.

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